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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,844	08/06/2001	Shujath M. Ali	DEX-0176	7509

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LICATLA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/787,844	**Applicant(s)** ALI ET AL.	
	Examiner MISOOK YU, Ph.D.	**Art Unit** 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *8,9,13-15,17-19 and 21-33*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

Misook Yu, 3/25/2005

Continuation of 3. NOTE: The amendment raises new issues that would require further consideration because the response argues that the claimed invention is enabled based on the IDS filed along with the amendment. The reply after final has not been entered because no convincing argument has been presented, showing why the IDS had not been provided with prior to final rejection with the most immediate prior reply and that consideration at this late stage would require new consideration of whether the claimed invention is enabled based on applicant's argument with the new IDS. It is recommended that RCE be filed in order to properly consider the IDS filed after the final Office action.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argues that the instantly claimed invention could be practiced without an undue experimentation as evidenced by the references in the newly filed IDS. These arguments do not overcome the rejection of record because the IDS filed after the final Office action has not been considered. The information disclosure statement filed 3/18/2005 fails to comply with 37 CFR 1.97(d). The IDS lacks a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered.

As stated before during the prosecution history, delivering a derivatized antibody (i.e. a radiopharmaceutical) for imaging purpose is not a trivial matter. A radiopharmaceutical requires testing to see whether the radiopharmaceutical specifically binds to the in vivo target in vivo; how the unbound radiopharmaceutical is cleared for minimizing unwanted high background. The instant specification has failed to teach with a reasonable certainty that the protein encoded by SEQ ID NO:1 is a gynecologic cancer antigen while the art (see Hooper et al., above) suggests that the protein encoded by SEQ ID NO:1 is a tumor suppressor. Low et al., (1995, Radiology, vol. 195, pages 391-400) also teach that in order to image an ovarian cancer (a species of a gynecologic cancer), selection of an antibody that specially binds to an ovarian cancer-associated antigen, is the first necessary step (see page 391 middle column; the authors selected an antibody targeting Tag-72, a previously known ovarian cancer antigen). Low et al., further teach accuracy of imaging using an antibody directed to a cancer antigen has to be evaluated against other known cancer detection methods such as histology or pathology (note page 393 under the heading "Pathologic Proof", and Table 3 at page 396) Likewise, Krag et al., (1993, Arch. Surg. Vol. 128, pages 819-23) teach method of imaging an ovarian cancer using a radio-labeled (i.e. indium 111-labeled) CYT-103 monoclonal antibody requires selection of an antibody capable of binding to an antigen that is over-expressed in an ovarian cancer (see page 820 under the heading "Patients, Materials, and Methods"). The instant application fails to teach whether SEQ ID NO:2 or a protein encoded by SEQ ID NO:1 is over-expressed in any gynecologic cancer, thus failing at the first required step leading to method of imaging a gynecologic cancer or delivering a derivatized antibody to gynecologic tumors or cancers.

Continuation of 13. Other: The information disclosure statement filed 3/18/2005 fails to comply with 37 CFR 1.97(d) because it lacks a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered..

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
3/29/05